

REMARKS

The amendment to the specification specifies a provisional patent application to which the present application claims priority, and which is incorporated in its entirety in the present application.

Further restriction requirement

The Examiner alleges that claims 113-115 and 117 belong in Group I (directed to, e.g., a computerized method) and has withdrawn those claims from consideration. Applicants respectfully traverse this restriction, and point out that claims 113-115 and 117 are directed to a KIT, not to a method. Thus, the claims belong to Group II (directed to kits); they should not have been withdrawn from consideration. Furthermore, the Examiner has withdrawn claim 118 as also belonging to Group I. Applicants point out that claim 118 is a method for using a kit of the elected claims. Therefore, we request that claim 118 be rejoined to the kit claims when the kit claims are found to be allowable. (*In re Ochiai*, 37 USPQ 2d 1127 (Fed. Cir. 1995); *In re Brouwer*, 37 USPQ2d 1663 (Fed. Cir. 1996)).

Applicants also note that the withdrawn claims depend from claim 97 of Group II and, as such, should be examined with that claim.

Applicants request that the "withdrawn" claims be examined along with the other "kit" claims, and that claim 118 be rejoined to the kit claims when the kit claims are deemed to be allowable.

The indefiniteness rejection

The Examiner alleges that the term "at least about" is indefinite. Applicants disagree with this rejection. It would be clear to a skilled worker that "at least about 6" agents clearly includes, e.g., at least 5, at least, 6 or at least 7 agents. Furthermore, the Examiner is referred to *Chemical Separation Technology Inc. v. United States*, 63 USPQ2d 625, 1114, which points out that "the use of the term 'about' in a claim does not render the claim *per se* indefinite." This decision distinguishes the interpretation of the term "about" from the interpretation of that term in the *Amgen v. Chugai* case that was cited by the Examiner to support this rejection.

Nevertheless, in an effort to expedite prosecution, the term "about" has been deleted from the claims. The rejection is thus rendered moot.

The anticipation rejection over USP 6,994,982 ("Watt")

1. A plurality of recombinant constructs, each of which comprises an expression control sequence from a coordinated system of interest (a plurality of expression control sequences) - (as recited, e.g., in present claim 97)

The Examiner has not pointed to a disclosure in the reference of an assay, or a kit for performing the assay, in which the effects of putative agents on a *plurality* of expression control sequences are detected in one assay. The reference certainly does not disclose a method or assay in which the plurality of expression control sequences are from genes of "a coordinated system of interest" (as recited, e.g., in claim 97).

In contrast to the Examiner's interpretation of the reference, the Watt reference is directed, e.g., to a method for screening putative mediators, modulators or modifiers of a "biological activity," e.g., a biological activity that is operably linked to a reporter molecule. See, e.g., col. 10, lines 26-47, which passage is discussed below in the following paragraph, and col. 12, lines 37-41. A "biological activity" is defined at col. 12, lines 52-54 of the reference as including "biological interactions leading to a physical association between two or more molecules or 'partners.'" This definition, as applied in the reference, appears to encompass a promoter element or other type of expression control sequence that can interact with a partner. See, e.g., the discussion of "promoters suitable for regulating the expression of the reporter molecule" at col. 27, line 28 to col. 28, line 10 of the reference.

In an embodiment of the method of the reference, the putative mediators or modulators are peptides ("amino acid sequences"), which are expressed from nucleic acid sequences that are operably linked to promoters. See, e.g., the passage at col. 10, lines 26-47 which was cited by the Examiner in the Office Action ("In a sixth embodiment, there is provided a method for identifying an *amino acid sequence* that is capable of modulating a biological activity ..."). In this method, a host is transformed with at least a first nucleotide sequence encoding a reporter molecule that is operably under the control of a "biological activity." The host also contains a second nucleotide sequence, under the

operable control of a suitable promoter sequence, wherein the second nucleotide sequence is capable of encoding an amino acid sequence that is capable of modulating the biological activity. The putative modulatory sequence, then, can act on the biological activity (an expression control sequence). In this method of the reference, the putative modulatory sequence is a peptide; it is not a polynucleotide expression control sequence. When the putative modulatory amino acid sequences are expressed, these expressed proteins or peptides are assayed to determine "those amino acids which are essential for modifying the reporter molecular activity." In embodiments of a method of the reference, multiple peptides - *e.g.* from an expression library in which the peptides are encoded by nucleic acids that are operatively linked to promoters - are screened. These sequences encoding peptides, or collections of multiple peptides, are sometimes referred to in the reference as part of a "gene fragment expression library," "fragments of genomes," "defined genomic sequences," or "random peptide library."

Contrary to the allegation by the Examiner, the discussion of "pluralities" of sequences in the reference (*e.g.* in the cited passages at col. 10, lines 55-62 and col. 31, lines 38-61) refers to different types of putative mediators or modulators, *not* to a plurality of expression control sequences. The Examiner does not identify any disclosure in the reference of a method or kit using a plurality of different types expression control sequences.

Note that new claim 119 further is further distinguished from the reference in its recitation of "*at least 5 recombinant constructs, each of which comprises an expression control sequence from a gene of a coordinated system of interest, operatively linked to a sequence encoding a reporter.*"

2. At least three agents from a first set of agents ... and at least three agents from a second set of agents... wherein said at least three agents from said first and second sets of agents are combined in an inter-set combinatorial fashion - (as recited, *e.g.*, in present claim 97)

In the presently claimed methods and kits, combinations of agents are used, which are known or predicted to act on at least one of defined expression control sequences. The reference does not suggest or disclose using *combinations* of agents, as presently claimed.

The Watt reference does not teach reagents that are used in a multivariate (multifactorial) assay, or that are present in a kit for performing such an assay, *e.g.* as recited in instant claim 97: "wherein *at least three agents* from a first set of agents and *at least three agents* from a second set of agents are combined in an inter-set combinatorial fashion."

An "inter-set combination" is described on page 14, lines 6-13 of the specification: "In other embodiments of the invention, stimuli from a first set and second set (or still further sets) of stimuli are exposed to each member of a plurality of biological entities in an "inter-set combinatorial fashion." That is, one or more stimuli of two sets are combined, for example pair-wise, three at a time, and so forth. For example, if the first set includes stimuli A-1, A-2, A-3 and A-4, and the second set includes B-1, B-2, B-3 and B-4, the following types of combinations of stimuli can be exposed to one of the biological entities: A-1 plus B-1; A-1 plus B-2; A-1 plus B-3; A-3 plus B-1; A-1 plus B-1 plus B-2; A-1 plus A-2 plus B-1 plus B-2, etc."

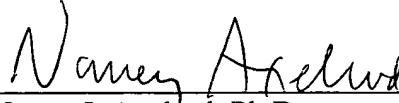
The Examiner does not point to a disclosure in the reference of an assay or a kit in which such combinations of multiple stimuli or agents are assembled.

For at least the reasons noted above, with regard to the two claim terms discussed above, the Watt reference fails to suggest or disclose all the material elements of the present claims, and thus fails to anticipate the claims. (*In re Marshall*, 198 USPQ 344 (CCPA, 1978)). It is requested that the anticipation rejection be withdrawn.

In view of the preceding arguments and amendments, the application is believed to be in condition for allowance, which action is respectfully requested.

No fee is believed to be due with this Reply. However, the Commissioner is hereby authorized to charge any fees association with this response or credit any overpayment to Deposit Account No. 22-0261.

Respectfully submitted,



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